

EXHIBIT 1

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and Sunovion Pharmaceuticals Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SUMITOMO DAINIPPON PHARMA CO.,
LTD. and SUNOVION
PHARMACEUTICALS INC.,

Plaintiffs,

v.

EMCURE PHARMACEUTICALS
LIMITED, et al.,

Defendants.

Civil Action No. 15-280 (SRC) (CLW)
Civil Action No. 15-281 (SRC) (CLW)
Civil Action No. 15-6401 (SRC) (CLW)
(Consolidated)

**SUNOVION'S PRELIMINARY CLAIM CONSTRUCTIONS
AND IDENTIFICATION OF SUPPORTING EVIDENCE**

Pursuant to the pretrial scheduling order entered in this case (D.I. 45), Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. (collectively, “Sunovion”) hereby set forth their Preliminary Claim Constructions and Identification of Supporting and Intrinsic Evidence as required by Local Patent Rule 4.2 (a)-(b) of the United States District Court for the District of New Jersey for the claim terms that Defendants Emcure Pharmaceuticals, Ltd. and Emcure Pharmaceuticals USA, Inc. (collectively, “Emcure”), Defendant InvaGen Pharmaceuticals, Inc. (“InvaGen”), and Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, “Teva”) assert should be construed by the Court.

Sunovion objects to providing preliminary proposed constructions to Emcure’s, InvaGen’s, and Teva’s proposed claim terms because Emcure, InvaGen, and Teva (collectively, “Defendants”) have failed to articulate sufficient reasons to disregard the plain and ordinary meaning of the claim terms of asserted Claim 14. Further, each of Defendants’ current claim construction positions are inconsistent with their Paragraph IV Notice Letters and their respective L. Pat. R. 3.3 and 3.6 contentions. Sunovion states that the claim terms proposed by Emcure, InvaGen, and Teva do not require further construction, and the disputed issues in this case can be resolved according to their plain meaning. *See, e.g., U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (claim construction is required only when constructions bear on the resolution of issues of infringement or validity).

Additionally, Sunovion objects to any attempt by Emcure, InvaGen, or Teva to introduce extrinsic evidence to claim construction, including, without limitation, dictionary definitions, learned treatises, prior art, and testimony of any witnesses, including expert witnesses. Sunovion believes that the intrinsic evidence, including the depiction and/or words in the disputed claim

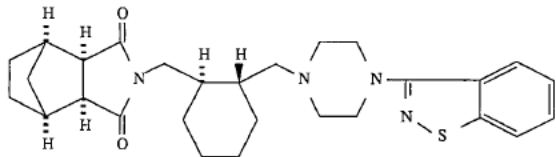
term, the other claims of the '372 patent, the specification of the '372 patent, and the prosecution history of the '372 patent, are clear. As a result, the claim terms should be understood in accordance with their plain meaning. Subject to this objection, Sunovion reserves the right to supplement its intrinsic evidence for claim constructions with extrinsic evidence in response to any extrinsic evidence Emcure, InvaGen, and/or Teva may attempt to introduce.

The below proposed claim constructions are preliminary and based on information presently available to Sunovion. Sunovion reserves the right to supplement and/or amend these constructions and evidence if Emcure's, InvaGen's, or Teva's current or subsequent constructions attempt to introduce any issues in this case not set forth in their respective L. Pat. R. 3.3 and 3.6 contentions. Sunovion reserves the right to supplement and/or amend its preliminary claim constructions based on the constructions proposed by Emcure, InvaGen, or Teva and/or any information that subsequently becomes available. Sunovion offers these preliminary constructions and supporting evidence for, and in the context of, this litigation only. Any constructions offered by Sunovion are not necessarily applicable to any future litigation.

I. PRELIMINARY CLAIM CONSTRUCTIONS

Subject to and without any waiver of the objections and statements above, and in further good-faith attempt to limit the number of disputes before the Court, Sunovion sets forth below its preliminary proposed constructions for the claim terms proposed by Emcure, InvaGen, and Teva pursuant to this Court's Scheduling Order and Local Patent Rule 4.2(a). Sunovion states that the claim terms should be understood by their "plain meaning" and based on the commonly understood meaning of the depiction and/or words included in the claim term, in the context of the '372 patent.

Based on the contentions of the parties, Sunovion does not believe any terms of the '372 patent require construction. To the extent that any term of the '372 patent identified by Emcure, InvaGen, and/or Teva is subject to claim construction proceedings, Sunovion sets forth below its preliminary proposed constructions.

U.S. Patent No. 5,532,372 (Claim 14)	
Claim Term or Phrase	Sunovion's Proposed Construction
<p>"The imide compound of the formula:</p>  <p>”</p>	<p>Plain meaning – refers to lurasidone, lurasidone's enantiomer, as well as mixtures thereof</p>
<p>“or an acid addition salt thereof”¹</p>	<p>Plain meaning</p>

II. EVIDENCE

Pursuant to this Court's Scheduling Order and Local Patent Rule 4.2(b), Sunovion identifies below the intrinsic and extrinsic evidence it may rely upon in support of its preliminary claim constructions. Sunovion reserves the right to rely upon additional evidence, including in response to Emcure's, InvaGen's, and/or Teva's proposed claim constructions and/or designation of evidence.

A. Intrinsic Evidence

- The specification of the '372 patent, including, without limitation: 3:3-4:43, 4:44-53, 11:38-65, 14:63-16:39, 27:35-40, 28:29-35, 30:30-32:23, and Example 12;
- The prosecution history of the patent-in-suit;

¹ Only InvaGen proposed this term for construction by the Court.

- The various claims of the '372 patent; and
- Portions of the intrinsic record that Sunovion may identify in response to any materials cited by Emcure, InvaGen, and/or Teva.

B. Extrinsic Evidence

As stated above, Sunovion objects to introducing extrinsic evidence in this case because the intrinsic evidence and plain meaning of the term are sufficiently clear. Subject to this objection, Sunovion reserves the right to introduce the following extrinsic evidence and any other extrinsic evidence not listed here to respond to any such evidence Emcure, InvaGen, and/or Teva may attempt to bring into this case:

- Emcure's Paragraph IV Notice Letter dated December 2, 2014;
- Emcure's L. Pat. R. 3.3 and 3.6 contentions dated August 4, 2015;
- InvaGen's Paragraph IV Notice Letter dated December 5, 2014;
- InvaGen's L. Pat. R. 3.3 and 3.6 contentions dated July 28, 2015;
- Teva's Paragraph IV Notice Letter dated July 13, 2015; and
- Teva's L. Pat. R. 3.3 and 3.6 contentions dated February 3, 2016.

Dated: April 6, 2016

By: s/ Charles M. Lizza
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EXHIBIT 2

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and Sunovion Pharmaceuticals Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SUMITOMO DAINIPPON PHARMA CO.,
LTD. and SUNOVION
PHARMACEUTICALS INC.,

Plaintiffs,

v.

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LIMITED, et al.,

Defendants.

Civil Action No. 15-280 (SRC) (CLW)
Civil Action No. 15-281 (SRC) (CLW)
Civil Action No. 15-6401 (SRC) (CLW)
(Consolidated)

**SUNOVION'S IDENTIFICATION OF
REBUTTAL CLAIM CONSTRUCTION EVIDENCE**

Pursuant to the pretrial scheduling order entered in this case (D.I. 45) and Local Patent Rule 4.2(c) of the United States District Court for the District of New Jersey, Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. (collectively, “Sunovion”) hereby set forth their Rebuttal Claim Construction Evidence for the claim term that Defendants Emcure Pharmaceuticals Ltd. and Emcure Pharmaceuticals USA, Inc. (collectively, “Emcure”), Defendant InvaGen Pharmaceuticals, Inc. (“InvaGen”), and Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, “Teva”) assert should be construed by the Court in their L. Pat. R. 4.2(b) Preliminary Claim Constructions and Supporting Evidence.

As an initial matter, Sunovion objects to providing rebuttal evidence for the claim term identified by Emcure, InvaGen, and Teva (collectively, “Defendants”) on the ground that the claim construction sought by Defendants constitute an inappropriate and unnecessary burden on the Court and the parties. Defendants have failed to articulate sufficient reasons to disregard the plain and ordinary meaning of the claim term of asserted Claim 14. As set forth in Sunovion’s Preliminary Claim Constructions, each of Defendants’ alleged claim construction position is inconsistent with their Paragraph IV Notice Letters and their respective L. Pat. R. 3.3 and 3.6 contentions.

Sunovion also objects to Defendants’ improper attempt to rely on and/or incorporate evidence identified by another defendant. Under L. Pat. R. 4.2(b), each defendant is required to identify with specificity all evidence that allegedly supports its constructions. Defendants are not permitted to rely on evidence not properly identified and/or produced under L. Pat. R. 4.2(b). Accordingly, Sunovion reserves the right to seek preclusion of any evidence sought to be offered

by Defendants that was not properly disclosed pursuant to L. Pat. R. 4.2(b) in their April 6, 2016 Preliminary Claim Constructions and Supporting Evidence.

In addition, the use of extrinsic evidence for claim construction is inappropriate in this case because the intrinsic evidence, including the depiction and/or words in the disputed claim term, the other claims of the '372 patent, the specification of the '372 patent, and the prosecution history of the '372 patent, are clear such that the disputed claim term should be understood in accordance with its plain meaning. As such, Sunovion objects to Defendants' attempts to introduce extrinsic evidence to claim construction, including, without limitation, articles, publications, textbooks, patents, new drug applications, prescribing information, and/or expert testimony. Sunovion reserves the right to seek preclusion of any expert opinions or testimony sought to be offered by Defendants that was not properly disclosed.

The evidence below is based upon the information presently available to Sunovion and is made in reliance on Defendants' proposed construction and the evidence it has offered in support thereof. Sunovion provides this rebuttal evidence in reliance on Defendants' current claim construction position which is inconsistent with their respective L. Pat. R. 3.3 and 3.6 contentions and their Paragraph IV Notice Letters.

EVIDENCE

Pursuant to this Court's Scheduling Order and Local Patent Rule 4.2(c), Sunovion identifies below the intrinsic and extrinsic evidence it may rely upon to rebut the construction proposed by Defendants. In addition to the evidence listed below, Sunovion may rely on any evidence cited by Defendants in their L. Pat. R. 4.2(b) and (c) disclosures as well as the context of

that evidence. Sunovion reserves the right to rely upon additional evidence, including in response to Defendants' designation of evidence opposing Sunovion's proposed construction.

A. Intrinsic Evidence

- The specification of the '372 patent, including, without limitation: 3:3-4:43, 4:44-53, 11:38-65, 12:31-13:9, 14:63-16:39, 27:35-40, 28:29-35, 30:30-32:23, Compound No. 206 in Table 7, and Examples 4, 6, 10, 12, 22, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 62, 64, 66, 67, 69, and 72;
- The prosecution history of the patent-in-suit, including, without limitation: LATUDA-00000676-82, LATUDA-00000688-92, and LATUDA-00000849-965; and
- The various claims of the '372 patent, including, without limitation: Claims 15 and 19.

B. Extrinsic Evidence

As stated above, Sunovion objects to introducing extrinsic evidence in this case because the intrinsic evidence and plain meaning of the proposed term for construction is sufficiently clear. Subject to this objection, Sunovion reserves the right to introduce the following extrinsic evidence and any other extrinsic evidence not listed here to respond to any such evidence Defendants may attempt to bring into this case:

- Emcure's Paragraph IV Notice Letter dated December 2, 2014;
- Emcure's Supplemental Paragraph IV Notice Letter dated June 16, 2015;
- Emcure's L. Pat. R. 3.3 and 3.6 contentions dated August 4, 2015;
- InvaGen's Paragraph IV Notice Letter dated December 5, 2014;
- InvaGen's Supplemental Paragraph IV Notice Letter dated June 18, 2015;
- InvaGen's L. Pat. R. 3.3 and 3.6 contentions dated July 28, 2015;
- Teva's Paragraph IV Notice Letter dated July 13, 2015; and
- Teva's L. Pat. R. 3.3 and 3.6 contentions dated February 3, 2016.

Sunovion reserves the right to call one or more experts to testify in rebuttal to any expert testimony Defendants may seek to introduce. Sunovion reserves the right to rely upon any documents relied upon by any expert testifying on Sunovion's or Defendants' behalf in connection with the *Markman* proceeding in this action.

Dated: April 20, 2016

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*Attorneys for Plaintiffs
Sumitomo Dainippon Pharma Co., Ltd.
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EXHIBIT 3

Salvatore Guerriero

From: DiSabatino, Dominick <dominickdisabatino@paulhastings.com>
Sent: Tuesday, April 26, 2016 2:34 PM
To: 'Kistler, David C.'; Hu, Christopher K.; Lessler, Jay; Heble, Nikhil A.; Salvatore Guerriero; Robert S. Silver; Pei-Ru Wey; Hardman, Cynthia; Levy, Ira J; Cipriano, Linnea P; Mayra Tarantino; Michael Patunas
Cc: Project LATUDA; 'Lizza, Charles M.'; 'Baton, William C.'; 'Sullivan, Sarah A.'; 'Moses, David L.'; Lucia, Jamie L.; Ratliff, Preston K.
Subject: Sunovion et al. v. Emcure et al., Civil Action No. 15-280 (consolidated action)
Attachments: Attachment.docx

Counsel,

Attached is Sunovion's portion of the draft L. Pat. R. 4.3 Joint Claim Construction and Prehearing Statement. In order to prepare the Joint Statement for submission, please let us have Defendants portion by this Friday, April 29. Also, please let us know if Defendants are available for a meet and confer on Monday, May 2 at 3 pm ET.

Very truly yours,

Dominick

*Please note our new address effective May 2, 2016:

200 Park Avenue, New York, NY 10166

PAUL
HASTINGS

Dominick P. DiSabatino | Associate, Litigation Department

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DRAFT

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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SUMITOMO DAINIPPON PHARMA
CO., LTD. and SUNOVION
PHARMACEUTICALS INC.,

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EMCURE PHARMACEUTICALS
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Defendants.

Civil Action No. 15-280 (SRC) (CLW)
Civil Action No. 15-281 (SRC) (CLW)
Civil Action No. 15-6401 (SRC) (CLW)
(Consolidated)

(Filed Electronically)

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. (collectively, “Sunovion”), Defendants Emcure Pharmaceuticals Ltd. and Emcure Pharmaceuticals USA, Inc. (collectively, “Emcure”), Defendant InvaGen Pharmaceuticals, Inc. (“InvaGen”), and Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, “Teva”) (together, “Defendants”) hereby submit their Joint Claim Construction and Prehearing Statement in accordance with the Court’s November 24, 2015 Pretrial Scheduling Order (D.I. 45) and Local Patent Rule 4.3.

I. BACKGROUND

This case arises out of the filing of ANDA Nos. 208058, 208028, and 208060 by Defendants Emcure, InvaGen, and Teva, respectively, with the U.S. Food and Drug Administration (“FDA”) seeking approval to market generic versions of a drug product containing lurasidone hydrochloride, the active ingredient of lurasidone hydrochloride tablets sold by Sunovion under the trade name LATUDA[®]. The LATUDA[®] (lurasidone hydrochloride) tablets are indicated for the treatment of schizophrenia and depressive episodes associated with Bipolar I Disorder (bipolar depression).

Sunovion alleges, among other things, that Defendants’ submission of ANDA Nos. 208058, 208028, and 208060 constitutes infringement of Claim 14 of U.S. Patent No. 5,532,372 (“the ’372 patent”). Defendants Emcure and Teva allege that asserted Claim 14 is invalid and not infringed. Defendant InvaGen alleges that asserted Claim 14 is invalid, but did not provide any non-infringement contentions under Local Patent Rule 3.6.

(a) Sunovion's Statement

Defendants proposed one claim term of asserted Claim 14 for construction by the Court. Sunovion did not propose any terms for construction by the Court. Sunovion does not believe claim construction is necessary because, among other things, Defendants have admitted that their proposed lurasidone hydrochloride products infringe Claim 14 of the '372 patent. *See, e.g.*, Emcure's Paragraph IV Notice Letter dated December 2, 2014 at 8; Emcure's Supplemental Paragraph IV Notice Letter dated June 16, 2015 at 13; InvaGen's Paragraph IV Notice Letter dated December 5, 2014 at 23-25; InvaGen's Supplemental Paragraph IV Notice Letter dated June 18, 2015 at 12-13; and Teva's Paragraph IV Notice Letter dated July 13, 2015 at 11.

Although Sunovion is following the Local Patent Rules in providing a position on claim construction, Sunovion reserves the right to object to the need for any claim construction proceeding with regard to the term proposed by Defendants for Claim 14 of the '372 patent and proposes its construction for this litigation only.

(b) Defendants' Statement

[Add statement here]

II. CONSTRUCTION OF TERMS

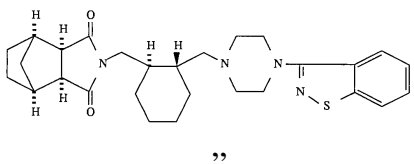
(a) The Construction of the Terms on Which the Parties Agree

In accordance with the Court's November 24, 2015 Pretrial Scheduling Order (D.I. 45) and Local Patent Rule 4.3(a), the parties agree that, other than the specific term identified below, the remaining term of Claim 14 of the '372 patent does not require

construction by the Court and that the plain and ordinary meaning of the terms should govern. The claim term of Claim 14 that the parties agree does not require construction, and should be given its plain and ordinary meaning is: “or an acid addition salt thereof.” The plain and ordinary meaning of this claim term includes for example, lurasidone hydrochloride.

(b) Each Party’s Proposed Construction of the Claim Term in Dispute

In accordance with the Court’s November 24, 2015 Pretrial Scheduling Order (D.I. 45) and Local Patent Rule 4.3(b), a claim chart is provided below identifying the claim term proposed for construction, subject to Sunovion’s statement as reflected in Paragraph I(a) of this Joint Claim Construction and Prehearing Statement, and the parties’ proposed constructions thereof. A chart identifying the intrinsic and extrinsic evidence that each party intends to rely upon in support of its respective construction is attached as Exhibit A.

U.S. Patent No. 5,532,372 (Claim 14)		
Claim Term or Phrase	Sunovion’s Proposed Construction	Defendants’ Proposed Construction
<p>“The imide compound of the formula:</p>  <p>”</p>	<p>Plain meaning – refers to lurasidone, lurasidone’s enantiomer, as well as mixtures thereof</p>	<p>A racemic mixture of two enantiomers of which the structural formula is representative</p>

(c) Claim Term Whose Construction Will be Most Significant or Dispositive

In accordance with the Court’s November 24, 2015 Pretrial Scheduling Order (D.I.

45) and Local Patent Rule 4.3(c), Sunovion does not believe that construction of any term of Claim 14 of the '372 patent will be case dispositive or substantially conducive to promoting settlement, including for the reasons described above.

(d) Anticipated Length of Time Necessary for the Claim Construction Hearing

The parties anticipate that the Court will be able to conduct a hearing on the construction of the identified claim term in no more than three to four hours.

(e) Identification of Witnesses for the Claim Construction Hearing

Sunovion does not anticipate calling any witnesses at the Claim Construction hearing. Further, Sunovion objects to any witness testimony proposed by Defendants as unnecessary because the intrinsic evidence and plain meaning of the proposed term for construction is sufficiently clear.

Dated: May 4, 2016

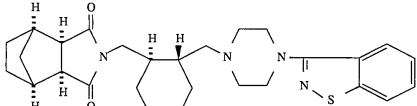
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Attorneys for Plaintiffs
Sumitomo Dainippon Pharma Co., Ltd.
and Sunovion Pharmaceuticals Inc.

EXHIBIT A**Evidence in Support of the Parties' Proposed Construction of Disputed Term**

U.S. Patent No. 5,532,372 (Claim 14)		
Claim Term or Phrase	Sunovion's Evidence	Defendants' Evidence
<p>"The imide compound of the formula:</p>  <p>"</p>	<p><u>Intrinsic Evidence</u></p> <p>The '372 patent specification, including, without limitation: 3:3-4:43, 4:44-53, 11:38-65, 12:31-13:9, 14:63-16:39, 27:35-40, 28:29-35, 30:30-32:23, Compound No. 206 in Table 7, and Examples 4, 6, 10, 12, 22, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 62, 64, 66, 67, 69, and 72.</p> <p>The prosecution history of the '372 patent, including, without limitation, LATUDA-00000676-82, LATUDA-00000688-92, and LATUDA-00000849-965.</p> <p>The various claims of the '372 patent, including, without limitation: Claims 15 and 19.</p> <p>Any intrinsic evidence cited by Emcure, InvaGen, and/or Teva in their Local Patent Rule exchanges as well as their context.</p> <p><u>Extrinsic Evidence</u></p> <p>Emcure's Paragraph IV Notice</p>	

U.S. Patent No. 5,532,372 (Claim 14)		
Claim Term or Phrase	Sunovion's Evidence	Defendants' Evidence
	<p>Letter dated December 2, 2014.</p> <p>Emcure's Supplemental Paragraph IV Notice Letter dated June 16, 2015.</p> <p>Emcure's L. Pat. R. 3.3 and 3.6 contentions dated August 4, 2015.</p> <p>InvaGen's Paragraph IV Notice Letter dated December 5, 2014.</p> <p>InvaGen's Supplemental Paragraph IV Notice Letter dated June 18, 2015.</p> <p>InvaGen's L. Pat. R. 3.3 and 3.6 contentions dated July 28, 2015.</p> <p>Teva's Paragraph IV Notice Letter dated July 13, 2015.</p> <p>Teva's L. Pat. R. 3.3 and 3.6 contentions dated February 3, 2016.</p> <p>Any evidence cited by Emcure, InvaGen, and/or Teva in their Local Patent Rule exchanges as well as their context.</p> <p>Any documents relied upon by any expert in connection with the <i>Markman</i> proceeding in this action.</p>	

EXHIBIT 4

Salvatore Guerriero

From: Yakub, Imtiaz <imtiaz Yakub@paulhastings.com>
Sent: Tuesday, May 03, 2016 2:55 PM
To: Hardman, Cynthia; 'Kistler, David C.'; Hu, Christopher K.; Lessler, Jay; Heble, Nikhil A.; Salvatore Guerriero; Robert S. Silver; Pei-Ru Wey; Levy, Ira J; Cipriano, Linnea P; Mayra Tarantino; Michael Patunas; Auerbach, Jonathan A
Cc: Project LATUDA; 'Lizza, Charles M.'; 'Baton, William C.'; 'Sullivan, Sarah A.'; 'Moses, David L.'; Lucia, Jamie L.; Ratliff, Preston K.; DiSabatino, Dominick
Subject: RE: Sunovion et al. v. Emcure et al., Civil Action No. 15-280 (consolidated action)
Attachments: Attachment.docx; redline.docx

Counsel,

As discussed, please find attached the revised draft Joint Statement in clean and redline to the version Defendants' provided on April 29.

Very truly yours,

Imtiaz

From: DiSabatino, Dominick
Sent: Monday, May 02, 2016 4:01 PM
To: Hardman, Cynthia; 'Kistler, David C.'; Hu, Christopher K.; Lessler, Jay; Heble, Nikhil A.; Salvatore Guerriero; Robert S. Silver; Pei-Ru Wey; Levy, Ira J; Cipriano, Linnea P; Mayra Tarantino; Michael Patunas; Auerbach, Jonathan A
Cc: Project LATUDA; 'Lizza, Charles M.'; 'Baton, William C.'; 'Sullivan, Sarah A.'; 'Moses, David L.'; Lucia, Jamie L.; Ratliff, Preston K.
Subject: RE: Sunovion et al. v. Emcure et al., Civil Action No. 15-280 (consolidated action)

Counsel,

Thank you for the meet and confer today. Further to our discussion, please let us know if any of the Defendants disagree with Sunovion's proposed construction of the claim term "or an addition salt thereof." If so, please let us have as soon as possible your proposed constructions for that claim term. Further, please let us know as soon as practicable whether Defendants will use both Drs. Baldwin and Lindsley, or which one of them Defendants will use for claim construction. Sunovion will use Dr. Stephen G. Davies, Professor of Organic Chemistry and Fellow of Magdalen College at the University of Oxford, as its witness for the disputed claim terms. Finally, as discussed, we will send you revisions to the draft Joint Statement tomorrow.

Very truly yours,

Dominick

From: DiSabatino, Dominick
Sent: Friday, April 29, 2016 10:07 AM
To: 'Hardman, Cynthia'; 'Kistler, David C.'; Hu, Christopher K.; Lessler, Jay; Heble, Nikhil A.; Salvatore Guerriero; Robert S. Silver; Pei-Ru Wey; Levy, Ira J; Cipriano, Linnea P; Mayra Tarantino; Michael Patunas; Auerbach, Jonathan A
Cc: Project LATUDA; 'Lizza, Charles M.'; 'Baton, William C.'; 'Sullivan, Sarah A.'; 'Moses, David L.'; Lucia, Jamie L.; Ratliff,

Preston K.

Subject: RE: Sunovion et al. v. Emcure et al., Civil Action No. 15-280 (consolidated action)

Counsel,

Please use the following dial-in information for our call on Monday at 3PM ET:

Dial-in: 1-800-308-2601

Passcode: 690076

Very truly yours,

Dominick

From: Hardman, Cynthia [<mailto:CHardman@goodwinprocter.com>]

Sent: Thursday, April 28, 2016 12:32 PM

To: DiSabatino, Dominick; 'Kistler, David C.'; Hu, Christopher K.; Lessler, Jay; Heble, Nikhil A.; Salvatore Guerriero; Robert S. Silver; Pei-Ru Wey; Levy, Ira J; Cipriano, Linnea P; Mayra Tarantino; Michael Patunas; Auerbach, Jonathan A

Cc: Project LATUDA; 'Lizza, Charles M.'; 'Baton, William C.'; 'Sullivan, Sarah A.'; 'Moses, David L.'; Lucia, Jamie L.; Ratliff, Preston K.

Subject: RE: Sunovion et al. v. Emcure et al., Civil Action No. 15-280 (consolidated action)

Dominick,

I understand that defendants are available to meet and confer on Monday at 3 pm.

Thanks,

Cynthia

From: DiSabatino, Dominick [<mailto:dominickdisabatino@paulhastings.com>]

Sent: Thursday, April 28, 2016 10:48 AM

To: 'Kistler, David C.'; Hu, Christopher K.; Lessler, Jay; Heble, Nikhil A.; Salvatore Guerriero; Robert S. Silver; Pei-Ru Wey; Hardman, Cynthia; Levy, Ira J; Cipriano, Linnea P; Mayra Tarantino; Michael Patunas

Cc: Project LATUDA; 'Lizza, Charles M.'; 'Baton, William C.'; 'Sullivan, Sarah A.'; 'Moses, David L.'; Lucia, Jamie L.; Ratliff, Preston K.

Subject: RE: Sunovion et al. v. Emcure et al., Civil Action No. 15-280 (consolidated action)

Counsel,

As a follow up to Sunovion's e-mail below, please confirm that Defendants will send us their portion of the Joint Statement by this Friday. Also, please confirm that Monday at 3 pm ET works for our L. Pat. R. 4.2(d) meet and confer.

Very truly yours,

Dominick

From: DiSabatino, Dominick

Sent: Tuesday, April 26, 2016 2:34 PM

To: 'Kistler, David C.'; Hu, Christopher K.; Lessler, Jay; Heble, Nikhil A.; Salvatore Guerriero; Robert S. Silver; Pei-Ru Wey; Hardman, Cynthia; Levy, Ira J; Cipriano, Linnea P; Mayra Tarantino; Michael Patunas

Cc: Project LATUDA; 'Lizza, Charles M.'; 'Baton, William C.'; 'Sullivan, Sarah A.'; 'Moses, David L.'; Lucia, Jamie L.; Ratliff, Preston K.

Subject: Sunovion et al. v. Emcure et al., Civil Action No. 15-280 (consolidated action)

Counsel,

Attached is Sunovion's portion of the draft L. Pat. R. 4.3 Joint Claim Construction and Prehearing Statement. In order to prepare the Joint Statement for submission, please let us have Defendants portion by this Friday, April 29. Also, please let us know if Defendants are available for a meet and confer on Monday, May 2 at 3 pm ET.

Very truly yours,

Dominick

*Please note our new address effective May 2, 2016:

200 Park Avenue, New York, NY 10166

PAUL

HASTINGS

Dominick P. DiSabatino | Associate, Litigation Department

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www.paulhastings.com

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This message is sent by a law firm and may contain information that is privileged or confidential. If you received this transmission in error, please notify the sender by reply e-mail and delete the message and any attachments.

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Style Definition: Body Text First Indent

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SUMITOMO DAINIPPON PHARMA
CO., LTD. and SUNOVION
PHARMACEUTICALS INC.,

Plaintiffs,

v.

EMCURE PHARMACEUTICALS
LIMITED, *et al.*,

Defendants.

Civil Action No. 15-280 (SRC) (CLW)
Civil Action No. 15-281 (SRC) (CLW)
Civil Action No. 15-6401 (SRC) (CLW)
(Consolidated)

(Filed Electronically)

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. (collectively, “Sunovion”), Defendants Emcure Pharmaceuticals Ltd. and Emcure Pharmaceuticals USA, Inc. (collectively, “Emcure”), Defendant InvaGen Pharmaceuticals, Inc. (“InvaGen”), and Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, “Teva”) (together, “Defendants”) hereby submit their Joint Claim Construction and Prehearing Statement in accordance with the Court’s November 24, 2015 Pretrial Scheduling Order (D.I. 45) and Local Patent Rule 4.3.

I. BACKGROUND

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This case arises out of the filing of ANDA Nos. 208058, 208028, and 208060 by Defendants Emcure, InvaGen, and Teva, respectively, with the U.S. Food and Drug Administration (“FDA”) seeking approval to market generic versions of a drug product containing lurasidone hydrochloride, the active ingredient of lurasidone hydrochloride tablets sold by Sunovion under the trade name LATUDA[®]. The LATUDA[®] (lurasidone hydrochloride) tablets are indicated for the treatment of schizophrenia and depressive episodes associated with Bipolar I Disorder (bipolar depression).

Sunovion alleges, among other things, that Defendants’ submission of ANDA Nos. 208058, 208028, and 208060 constitutes infringement of Claim 14 of U.S. Patent No. 5,532,372 (“the ’372 patent”). Defendants deny all salient allegations asserted by Sunovion in its Complaints and contentions. Defendants Emcure and Teva allege that asserted Claim 14 is invalid and not infringed. Defendant InvaGen alleges that asserted Claim 14 is invalid, but did not provide any non-infringement contentions. [Sunovion](#)

believes that InvaGen is no longer permitted under the Local Patent ~~Rule 3.6~~Rules to
provide any such contentions. InvaGen expressly reserves the right to amend its
 contentions, including the right to assert non-infringement contentions, pursuant to L. Pat.
 R. 3.7.

(a) Sunovion's Statement

~~Defendants proposed one~~Two claim ~~term~~terms of asserted Claim 14 have been
proposed for construction ~~by the Court. Sunovion did not propose any terms for~~
~~construction by the Court.~~ Sunovion does not believe claim construction is necessary
 because, among other things, Defendants have admitted that their proposed lurasidone
 hydrochloride products infringe Claim 14 of the '372 patent. *See, e.g.*, Emcure's
 Paragraph IV Notice Letter dated December 2, 2014 at 8; Emcure's Supplemental
 Paragraph IV Notice Letter dated June 16, 2015 at 13; InvaGen's Paragraph IV Notice
 Letter dated December 5, 2014 at 23-25; InvaGen's Supplemental Paragraph IV Notice
 Letter dated June 18, 2015 at 12-13; and Teva's Paragraph IV Notice Letter dated July 13,
 2015 at 11.

Although Sunovion is following the Local Patent Rules in providing a position on
 claim construction, Sunovion reserves the right to object to the need for any claim
 construction proceeding with regard to the ~~term~~terms proposed by Defendants for Claim
 14 of the '372 patent and proposes its ~~construction~~constructions for this litigation only.

(b) Defendants' Statement

Defendants assert that one claim term requires construction because – under the proper construction of Claim 14 – their proposed products do not infringe the only claim asserted in this litigation. Defendants strongly disagree with Sunovion's statement that "Defendants have admitted their proposed lurasidone hydrochloride products infringe Claim 14 of the '372 patent," as Defendants' notice letters and detailed statements make no such admission. Further, contrary to Sunovion's statement, Defendants are neither limited to, nor required to assert, only the defense(s) stated in their notice letters. Finally, claim construction is also required because Plaintiffs' alleged "plain meaning" is not a plain meaning in the relevant field, ~~is~~ inconsistent with the intrinsic evidence and is disputed by Defendants.

II. CONSTRUCTION OF TERMS

(a) The Construction of the Terms on Which the Parties Agree

In accordance with the Court's November 24, 2015 Pretrial Scheduling Order (D.I. ~~45~~) and Local Patent Rule 4.3(a), the parties agree ~~state~~ that, ~~other than the specific term identified below, the remaining term~~ there are no claim terms of asserted Claim 14 of the '372 patent does not require on which the parties agree to a construction ~~by the Court~~ and that the plain and ordinary meaning of the terms should govern. The claim term of Claim 14 that the parties agree does not require construction, and should be given its plain and ordinary meaning is: "or an acid addition salt thereof."

(b) Each Party's Proposed Construction of the Claim ~~Term~~ Terms in

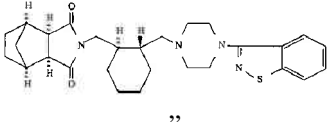
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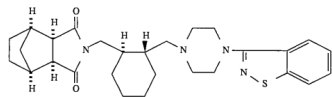
Dispute

In accordance with the Court's November 24, 2015 Pretrial Scheduling Order (D.I. 45) and Local Patent Rule 4.3(b), a claim chart is provided below identifying the claim ~~term~~terms proposed for construction, subject to the parties' respective statements in Paragraph I of this Joint Claim Construction and Prehearing Statement, and the parties' proposed constructions thereof. A chart identifying the intrinsic and extrinsic evidence that each party intends to rely upon in support of its respective ~~construction~~constructions is attached as Exhibit A.

U.S. Patent No. 5,532,372 (Claim 14)			Formatted Table
Claim Term or Phrase	Sunovion's Proposed Construction	Defendants' Proposed Construction	
<p>"The imide compound of the formula:</p>  <p>"</p>	<p>Plain<u>plain</u> meaning – refers to lurasidone, lurasidone's enantiomer, as well as mixtures thereof</p>	<p>A racemic mixture of two enantiomers of which the structural formula is representative</p>	
<p><u>"or an acid addition salt thereof"</u></p>	<p><u>plain meaning – includes for example, lurasidone hydrochloride</u></p>		<p>Formatted: Space Before: 6 pt, After: 6 pt</p> <p>Formatted: Left, Indent: Left: 0.23", Right: 0.36", Space Before: 6 pt, After: 12 pt, Widow/Orphan control, Keep with next, Keep lines together, Adjust space between Latin and Asian text, Adjust space between Asian text and numbers</p> <p>Formatted Table</p>

(c) **Claim Term Whose Construction Will be Most Significant or Dispositive**

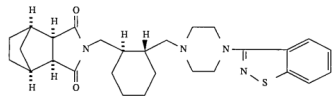
In accordance with the Court's November 24, 2015 Pretrial Scheduling Order (D.I. 45) and Local Patent Rule 4.3(c), ~~Defendants believe that proper construction of the phrase "[t]he imide compound of the formula:~~



~~”, will be significant; and may be dispositive.~~

Sunovion, ~~however,~~ does not believe that construction of any term of Claim 14 of the '372 patent will be case dispositive or substantially conducive to promoting settlement. ~~-Defendants, however, believe that proper construction of the phrase~~

~~“[t]he imide compound of the formula:~~



~~”, will be significant; and may be dispositive.~~

(d) **Anticipated Length of Time Necessary for the Claim Construction Hearing**

The parties anticipate that the Court will be able to conduct a hearing on the construction of the identified claim ~~term~~ terms in approximately four hours.

(e) **Identification of Witnesses for the Claim Construction Hearing**

Sunovion ~~does not anticipate calling any witnesses at the Claim Construction hearing. Further, Sunovion objects to any~~ believes that witness testimony ~~proposed by~~

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~~Defendants as is~~ unnecessary because the intrinsic evidence and plain meaning of the proposed ~~term~~ terms for construction ~~is are~~ sufficiently clear. Defendants, however, insist that extrinsic evidence in the form of witness testimony should be presented to the Court in order to construe the disputed claim terms. Therefore, Sunovion identifies Dr. Stephen G. Davies, Waynflete Professor of Organic Chemistry and Fellow of Magdalen College, University of Oxford, as an expert in chemistry to testify regarding how a person of ordinary skill in the art would have understood the disputed claim terms.

Defendants anticipate calling Dr. Stephen Baldwin and/or Craig W. Lindsley, Ph.D. as witnesses at the Claim Construction hearing to testify on the matters described in Exhibit A.

Dated: May 4, 2016

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Teva Pharmaceutical Industries, Ltd.*

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USA, Inc.) and Emcure Pharmaceuticals
Ltd.*

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(212) 318-6000

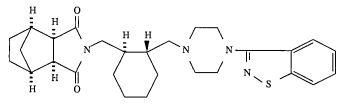
*Attorneys for Plaintiffs
Sumitomo Dainippon Pharma Co.,
Ltd. and Sunovion Pharmaceuticals
Inc.*

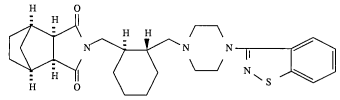
By:
Salvatore Guerriero
CAESAR RIVISE, PC
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12th Floor - Seven Penn Center
Philadelphia, PA 19103-2212
(215) 567-2010
sguerriero@crbcp.com

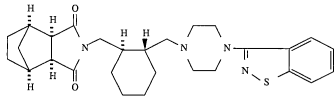
Of Counsel:
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Pei-Ru Wey
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Philadelphia, PA 19103-2212
(215) 567-2010

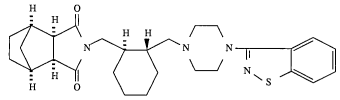
*Attorneys for Defendant
InvaGen Pharmaceuticals, Inc.*

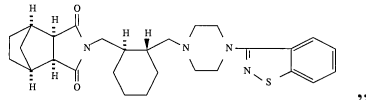
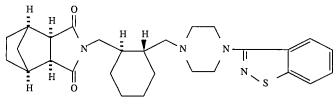
EXHIBIT A**Evidence in Support of the Parties' Proposed Construction of Disputed ~~Term~~ Terms**

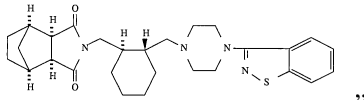
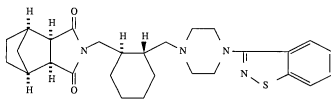
U.S. Patent No. 5,532,372 (Claim 14)	
Claim Term or Phrase	
<p>“The imide compound of the formula:</p>  <p>”</p>	
Sunovion's Evidence	Defendants' Evidence
<p><u>Intrinsic Evidence</u></p> <p>The '372 patent specification, including, without limitation: 3:3-4:43, 4:44-53, 11:38-65, 12:31-13:9, 14:63-16:39, 27:35-40, 28:29-35, 30:30-32:23, Compound No. 206 in Table 7, and Examples 4, 6, 10, 12, 22, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 62, 64, 66, 67, 69, and 72.</p> <p>The prosecution history of the '372 patent, including, without limitation, LATUDA-00000676-82, LATUDA-00000688-92, and LATUDA-00000849-965.</p> <p>The various claims of the '372 patent, including, without limitation: Claims 15 and 19.</p> <p>Any<u>The</u> intrinsic evidence cited by Emcure, InvaGen, and/or Teva in their Local Patent Rule exchanges as well as their context.</p> <p><u>Extrinsic Evidence</u></p>	<p><u>Intrinsic Evidence</u></p> <p>'372 patent.</p> <p>'372 patent specification, including:</p> <p>'372 patent, col. 11, lines 38-44.</p> <p>'372 patent, col. 12, line 29-col. 13, line 10.</p> <p>'372 patent, col. 13, lines 11-25.</p> <p>'372 patent, col. 13, line 60-col. 14, line 7.</p> <p>'372 patent, col. 14, lines 10-38.</p> <p>'372 patent, col. 14, lines 40-55.</p> <p>'372 patent, col. 14, line 63-col. 15, line 66.</p> <p>'372 patent, col. 16, line 42-col. 17, line 42.</p> <p>'372 patent, col. 17, line 45-col. 19, line 67.</p> <p>'372 patent, col. 27, lines 25-40.</p> <p>'372 patent, col. 29, lines 45-65</p> <p>'372 patent, Example 1-(a), col. 30, line 30-col. 31, line 9.</p> <p>'372 patent, Example 1-(b), col. 31, lines 11-24.</p>

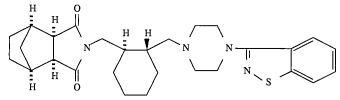
U.S. Patent No. 5,532,372 (Claim 14)	
Claim Term or Phrase	
<p>“The imide compound of the formula:</p>  <p>”</p>	
Sunovion's Evidence	Defendants' Evidence
Emcure's Paragraph IV Notice Letter dated December 2, 2014.	'372 patent, Example 1-(c), col. 31, lines 25-55.
Emcure's Supplemental Paragraph IV Notice Letter dated June 16, 2015.	'372 patent, Example 1-(d), col. 32, lines 1-14.
Emcure's L. Pat. R. 3.3 and 3.6 contentions dated August 4, 2015.	'372 patent, Example 1-(e), col. 32, lines 17-23
InvaGen's Paragraph IV Notice Letter dated December 5, 2014.	'372 patent, col. 32, lines 25-52.
InvaGen's Supplemental Paragraph IV Notice Letter dated June 18, 2015.	'372 patent, col. 32, line 55-col. 33, line 19.
InvaGen's L. Pat. R. 3.3 and 3.6 contentions dated July 28, 2015.	'372 patent at Tables 9 and 10.
Teva's Paragraph IV Notice Letter dated July 13, 2015.	'372 patent, Table 9, Example No. 15, Objective Compound No. 119.
Teva's L. Pat. R. 3.3 and 3.6 contentions dated February 3, 2016.	'372 patent, Table 9, Example No. 50, Objective Compound No. 154.
Any Expert testimony from Dr. Stephen G. Davies, Waynflete Professor of Organic Chemistry and Fellow of Magdalen College, University of Oxford, regarding how a person of ordinary skill in the art would have understood the disputed claim term. Dr. Davies can explain	'372 patent, Table 9, Example No. 72, Objective Compound No. 176.
	'372 patent, Claim 14.
	'372 patent, Claim 15.
	'372 patent, Claim 16.
	'372 patent, Claim 17.
	'372 patent, Claim 18.
	'372 patent, Claim 19.
	Prosecution History of the '372 patent, including:
	April 3, 1992 Requirement for Restriction/Election.
	April 29, 1992 Amendment.

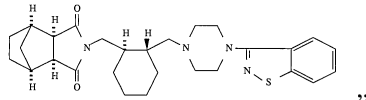
U.S. Patent No. 5,532,372 (Claim 14)	
Claim Term or Phrase	
<p>“The imide compound of the formula:</p> 	
Sunovion's Evidence	Defendants' Evidence
<p>that the disputed claim term, read in light of the '372 patent specification, would have been understood by a person of ordinary skill in the art to refer to lurasidone, lurasidone's enantiomer, as well as mixtures thereof.</p> <p>The evidence cited by Emcure, InvaGen, and/or Teva in their Local Patent Rule exchanges as well as their context.</p> <p>Any documents relied upon by any expert in connection with the Markman claim construction proceeding in this action.</p>	<p>May 15, 1992 Requirement for Restriction/Election.</p> <p>June 10, 1992 Amendment.</p> <p>August 10, 1992 Requirement for Restriction/Election.</p> <p>September 10, 1992 Amendment.</p> <p>November 27, 1992 Non-Final Rejection.</p> <p>March 1, 1993 Amendment including, without limitation, new Claim 27.</p> <p>August 30, 1993 Transmittal of New Application including, without limitation, Claims 11-27.</p> <p>August 30, 1994 Non-Final Rejection.</p> <p>Declaration of Yukihiro Ohno submitted in conjunction with December 29, 1994 Amendment including, without limitation, pages 2-4.</p> <p>December 12, 1994 Amendment including, without limitation, page 8.</p> <p>February 28, 1995 Requirement for Restriction/Election.</p> <p>March 30, 1995 Amendment including, without limitation, pages 2-3.</p> <p>June 16, 1995 Requirement for Restriction/Election.</p>

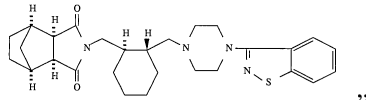
U.S. Patent No. 5,532,372 (Claim 14)	
Claim Term or Phrase	
<p>“The imide compound of the formula:</p> 	
Sunovion's Evidence	Defendants' Evidence
	<p>July 17, 1995 Amendment including, without limitation, page 1.</p> <p>August 8, 1995 Non-Final Rejection.</p> <p>November 14, 1995 Amendment.</p> <p>February 1, 1996 Notice of Allowance including, without limitation, allowed Claim 27, renumbered as Claim 14.</p> <p><u>Extrinsic Evidence</u></p> <p>Defendants may rely on the following articles, publications, patents, and other materials as extrinsic evidence.</p> <p>U.S. Patent Application Publication No. 2011/0183993A1 published July 28, 2011.</p> <p>Introduction To Organic Chemistry, Streitweiser and Heathcock, Macmillan, New York, Third Edition, 1985, page 218.</p> <p>Baraldi et al., <i>J. Org. Chem.</i> 1985, 50, 23-29.</p> <p>Williams et al., <i>J. Org. Chem.</i> 1985, 50, 91-97.</p> <p>White & Burton, <i>J. Org. Chem.</i> 1985, 50, 357-364.</p> <p>Schwartz & Willbrand, <i>J. Org. Chem.</i> 1985, 50, 1359-1365.</p> <p>Hall & Roush, <i>J. Org. Chem.</i> 1982, 47, 4611-4621.</p>

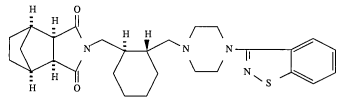
U.S. Patent No. 5,532,372 (Claim 14)	
Claim Term or Phrase	
<p>“The imide compound of the formula:</p>  <p>”</p>	
Sunovion's Evidence	Defendants' Evidence
	<p>Roush & Gillis, <i>J. Org. Chem.</i> 1982, 47, 4825-4829.</p> <p>Roush & D'Ambra, <i>J. Am. Chem. Soc.</i> 1983, 105, 1058-1060.</p> <p>Clive, <i>J. Org. Chem.</i> 1994, 59, 1396-1406.</p> <p>Organic Chemistry, Jones, M., Jr., New York, NY: W.W. Norton & Company, Inc., Second Edition, 1997, page 188.</p> <p>Organic Chemistry: Structure and Function, Vollhardt & Schore, New York, NY: W.H. Freeman and Company, Sixth Edition, 2010, page 201.</p> <p>Expert opinions about the level of ordinary skill in the art, the state of the relevant art, and the meaning of “the imide compound of the formula:</p>  <p>to a person of ordinary skill in the art at the time of filing date of the patent.</p> <p>Expert opinions that, based on the cited intrinsic and extrinsic evidence, the level of ordinary skill in the art, the state of the relevant art, and the meaning of</p>

U.S. Patent No. 5,532,372 (Claim 14)	
Claim Term or Phrase	
<p>“The imide compound of the formula:</p> 	
Sunovion's Evidence	Defendants' Evidence
	<p>“the imide compound of the formula:</p>  <p>to a person of ordinary skill in the art at the time of filing date of the '372 patent, Plaintiffs' proposed construction should not be adopted.</p> <p>Monthly Research Report, December 1991 (LATUDA-00002084-00002094).</p> <p>Documents submitted as part of the New Drug Application for the compound known as lurasidone.</p> <p>Extrinsic evidence identified by other defendants in litigations brought by plaintiffs involving the '372 patent.</p> <p>Defendants may also rely on extrinsic evidence in the form of expert testimony, the substance of which is described below:</p> <ol style="list-style-type: none"> 1. Example 1-(a) of the '372 patent (col. 30, line 30 to col. 31, line 9) describes the production of Compound No. 101. Compound (101) is the result

U.S. Patent No. 5,532,372 (Claim 14)	
Claim Term or Phrase	
<p>“The imide compound of the formula:</p>  <p>”</p>	
Sunovion's Evidence	Defendants' Evidence
	<p>of a synthesis involving Compound (201) and Compound (251).</p> <p>2. Although Compound (251) has asymmetric (or stereogenic) carbon atoms, it has a plane of symmetry and therefore does not confer chirality to the product, Compound (101).</p> <p>3. Compound (201), based on the description in Reference Example 1-(a), is a racemic mixture of optical isomers, since it is derived from trans-1,2-bis(hydroxymethyl)cyclohexane (2). There is no indication in the '372 patent that Compound (2), or any of the other intermediate compounds (Compounds (1) and (3)) in the preparation of Compound (201), has been resolved into one of its constituent enantiomers. The synthesis of Compound (201) is described at column 14, line 63 to column 15, line 66, and the structure is depicted at column 15, lines 25-34. The structure of Compound (201) is also depicted at column 30, lines 50-55. Compound (201) is necessarily a racemic mixture based on the description provided in Reference Example 1-(a)</p> <p>4. Compound (101) is also a racemic mixture based on the description of its chemical precursors and synthesis in the '372 patent. The '372 patent</p>

U.S. Patent No. 5,532,372 (Claim 14)	
Claim Term or Phrase	
<p>“The imide compound of the formula:</p>  <p>”</p>	
Sunovion's Evidence	Defendants' Evidence
	<p>illustrates Compound (101), a racemic mixture with two optical isomers, at the bottom of column 30. This depiction is consistent with the way in which the '372 patent illustrates other racemic mixtures, such as Compound (201). This method of depicting racemic mixtures is not unique to Sumitomo, as can be seen in the technical references identified above.</p> <p>5. The compound depicted in claim 14 of the '372 patent is identical to the free base of the compound depicted in column 30 that is labeled as and referred to as Compound (101), a racemic mixture.</p> <p>6. The preparation of Compounds (102), (103), (104) and (105) is described in the '372 patent at column 31, line 10 to column 32, line 22. Compounds (102), (103), (104) and (105) are each salts of a particular optical isomer making up the racemic mixture of Compound (101). Specifically, Compound (102) (Example 1-(b)) is a (+)-isomer of Compound (101) in the form of an <i>L</i>-tartrate salt; Compound (103) (Example 1-(c)) is a (-)-isomer of Compound (101) in the form of a <i>D</i>-tartrate salt; Compound (104) (Example 1-(d)) is a (+)-isomer of Compound (101) in the form of a hydrochloride salt; and Compound (105) (Example 1-(e)) is a (-)-isomer of Compound (101) in the form of a</p>

U.S. Patent No. 5,532,372 (Claim 14)	
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<p>“The imide compound of the formula:</p>  <p>”</p>	
Sunovion's Evidence	Defendants' Evidence
	<p>hydrochloride salt. Compounds (102) and (103) have equal but opposite optical rotations, further confirming that Compound (101) is a racemic mixture. Likewise, compounds (104) and (105) have equal but opposite optical rotations.</p> <p>7. The '372 patent treats Compound 101 (a racemic mixture) and Compound 105 (an optical isomer of Compound 101) as chemically distinct compounds. For example, the compounds were given unique numbers and tested separately and shown to have different properties, including different binding affinities (K_i) as shown in Table 2.</p> <p>8. The specification also uses structural formulas similar to that of Compound (101) to refer to other racemic mixtures. While all of the Objective Compounds in Table 9 of the '372 patent are chiral, there is no indication that any of them is a single optical isomer. To the contrary, the compounds used to prepare these Objective Compounds, as with the compounds for preparing Compound (101), indicate that they are racemic mixtures. For example, Objective Compound (112) in Table 9 is prepared from Compounds (253) and (201). Compound (201) as discussed above is a racemic mixture. Like Compound (251), Compound (253) has a plane of symmetry and</p>

U.S. Patent No. 5,532,372 (Claim 14)	
Claim Term or Phrase	
<p>“The imide compound of the formula:</p>  <p>”</p>	
Sunovion's Evidence	Defendants' Evidence
	<p>therefore does not confer chirality to the product, Objective Compound (112). The resulting Objective Compound (112) is therefore a racemic mixture.</p> <p>9. While Table 10 provides physicochemical data for the Objective Compounds of Table 9, it does not provide any measurement of their optical rotations, $[\alpha]$. If the compounds had been resolved, it would be expected that such optical rotation measurements would be reported.</p>

<u>U.S. Patent No. 5,532,372 (Claim 14)</u>	
<u>Claim Term or Phrase</u>	
<u>“or an acid addition salt thereof”</u>	
<u>Sunovion's Evidence</u>	<u>Defendants' Evidence</u>
<u>Intrinsic Evidence</u> <u>The '372 patent specification, including, without limitation: 3:3-4:43, 4:44-53, 11:38-65,</u>	

<u>U.S. Patent No. 5,532,372 (Claim 14)</u>	
<u>Claim Term or Phrase</u>	
<u>“or an acid addition salt thereof”</u>	
<u>Sunovion’s Evidence</u>	<u>Defendants’ Evidence</u>
<p><u>12:31-13:9, 14:63-16:39, 27:35-40, 28:29-35, 30:30-32:23, Compound No. 206 in Table 7, and Examples 4, 6, 10, 12, 22, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 62, 64, 66, 67, 69, and 72.</u></p> <p><u>The prosecution history of the ’372 patent, including, without limitation, LATUDA-00000676-82, LATUDA-00000688-92, and LATUDA-00000849-965.</u></p> <p><u>The various claims of the ’372 patent, including, without limitation: Claims 15 and 19.</u></p> <p><u>The intrinsic evidence cited by Emcure, InvaGen, and/or Teva in their Local Patent Rule exchanges as well as their context.</u></p> <p><u>Extrinsic Evidence</u></p> <p><u>Emcure’s Paragraph IV Notice Letter dated December 2, 2014.</u></p> <p><u>Emcure’s Supplemental Paragraph IV Notice Letter dated June 16, 2015.</u></p> <p><u>Emcure’s L. Pat. R. 3.3 and 3.6 contentions dated August 4, 2015.</u></p> <p><u>InvaGen’s Paragraph IV Notice Letter dated December 5, 2014.</u></p> <p><u>InvaGen’s Supplemental Paragraph IV Notice</u></p>	

<u>U.S. Patent No. 5,532,372 (Claim 14)</u>	
<u>Claim Term or Phrase</u>	
<u>“or an acid addition salt thereof”</u>	
<u>Sunovion’s Evidence</u>	<u>Defendants’ Evidence</u>
<p><u>Letter dated June 18, 2015.</u></p> <p><u>InvaGen’s L. Pat. R. 3.3 and 3.6 contentions dated July 28, 2015.</u></p> <p><u>Teva’s Paragraph IV Notice Letter dated July 13, 2015.</u></p> <p><u>Teva’s L. Pat. R. 3.3 and 3.6 contentions dated February 3, 2016.</u></p> <p><u>Expert testimony from Dr. Stephen G. Davies, Waynflete Professor of Organic Chemistry and Fellow of Magdalen College, University of Oxford, regarding how a person of ordinary skill in the art would have understood the disputed claim term. Dr. Davies can explain that the disputed claim term, read in light of the ‘372 patent specification, would have been understood by a person of ordinary skill in the art to refer to acid addition salts such as lurasidone hydrochloride.</u></p> <p><u>The evidence cited by Emcure, InvaGen, and/or Teva in their Local Patent Rule exchanges as well as their context.</u></p> <p><u>Any documents relied upon by any expert in connection with the claim construction proceeding in this action.</u></p>	